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Purpose: This standard operating procedure (SOP) details the procedures for performing biosafety laboratory inspections.

References:

NIH Guidelines

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Ed.

https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

BSL-1 Checklist: <https://www.jmu.edu/researchintegrity/biosafety/forms/ibc-biosafety-1-checklist.doc>

BSL-2 Checklist: <https://www.jmu.edu/researchintegrity/biosafety/forms/ibc-biosafety-2-checklist.doc>

Inspection Guidance: <https://www.jmu.edu/researchintegrity/biosafety/forms/ibc-inspection-guidance.pdf>

Exempt Form: <https://www.jmu.edu/researchintegrity/biosafety/forms/ibc-exempt.pdf>

Conditions: Lab work associated with microbiological agents is performed in the space.

Procedures:

Pre-Approval

1. Principal investigator (PI) identifies affiliated lab locations when submitting a research protocol for approval via the eRA system.
2. Once the protocol has been submitted to the Institutional Biosafety Committee (IBC) for review, the entire committee or a subset thereof schedules a time to perform a preapproval inspection of the laboratory facility/facilities.
3. PIs are strongly encouraged to be present and participate in the inspection.
4. Either a BSL-1 or BSL-2 checklist will be used to guide the inspection, depending on the biosafety level of the proposed work.
5. Any questions or observations made during the inspection will be documented on the checklist. If the PI is present and can address the noted issues, the resolution will be included on the checklist and labeled as “addressed during inspection.”
6. If the PI is not present, the checklist will be provided to the PI who will have 7 days to provide written confirmation to the IBC that the issues/questions have been resolved and how. For observations necessitating more complex solutions (i.e. that may require equipment modifications or involvement of



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Facilities Management), within the 7 days the PI must propose a plan, including completion dates, for addressing the checklist observations and provide that to the IBC for consideration.

7. If the observations have been satisfactorily resolved and there are no outstanding protocol issues, the research protocol will be electronically recommended for approval and voted upon at the next IBC meeting.
8. If the observations have not been satisfactorily resolved or the proposed plan is not acceptable, the IBC chair will communicate the reasons why back to the PI within 7 days of the IBC making that determination. The research protocol will not be electronically approved or voted upon until the observations are resolved or an acceptable plan has been provided to the IBC.
9. If a plan is provided, the PI must provide the IBC with updates and ensure milestones are achieved according to the plan timeline. Failure to provide the IBC with confirmation that a milestone has been achieved or satisfactory justification for the delay within 7 days of a completion date provided in the plan will result in notification to the PI and Area Unit Head (AUH).
10. Failure to provide written confirmation of completion or satisfactory justification for the delay of a missed milestone within 7 days following AUH notification, will result in protocol suspension and notification of protocol suspension to the appropriate college dean and Vice Provost for Research, Economic Development and Innovation (VPREDI).

Annual Inspections

1. As part of the annual renewal of active biosafety protocols, an inspection will be scheduled by the full IBC or a subset thereof.
2. PIs are strongly encouraged to be present and participate in the inspection.
3. Either a BSL-1 or BSL-2 checklist will be used to guide the inspection, depending on the biosafety level of the proposed work.
4. Any questions or observations made during the inspection will be documented on the checklist. If the PI is present and can address the noted issues, the resolution will be included on the checklist and labeled as “addressed during inspection.”
5. If the PI is not present, the checklist will be provided to the PI who will have 7 days to provide written confirmation to the IBC that the issues/questions have been resolved and how. For observations necessitating more complex solutions (i.e. that may require equipment modifications or involvement of Facilities Management), within the 7 days the PI must propose a plan, including completion dates, for addressing the checklist observations and provide that to the IBC for consideration.
6. If the observations have been satisfactorily resolved and there are no outstanding protocol issues, the research protocol will be renewed for another year.
7. If the observations have not been satisfactorily resolved or the proposed plan is not acceptable, the IBC chair will communicate the reasons why back to the PI AUH within 7 days.
8. The PI will have an additional 7 days to provide written confirmation that the issues have been satisfactorily resolved or provide a properly amended plan to the IBC for approval.



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- The IBC will review the written confirmation or amended plan within 7 days and notify the PI. If accepted by the IBC and there are no outstanding protocol issues, the research protocol will be renewed for another year.
- Failure by the PI to provide a written confirmation that inspection issues have been satisfactorily resolved, or provide a properly amended plan with 7 days following notification to the AUH, or if additional milestones in the same plan are subsequently missed without notification and proper justification to the IBC, will result in the associated protocol being suspended and notification of the protocol suspension provided to the appropriate college dean and the VPREDI.

For Cause Inspections

There are occasions outside of protocol pre-approval or renewal that may warrant an inspection, including but not limited to:

- Research Integrity or a member of the IBC receives a formal complaint of unsafe biosafety conditions or noncompliance with a registered/approved IBC protocol.
- As part of the incident investigation following an incident in any lab where biosafety work is performed (exempt, BSL-1 or BSL-2). Depending on the nature of the incident, the inspection scope may extend beyond the purview of the IBC and necessitate participation by other subject matter experts.
- Submission of a substantive protocol amendment, which would follow the same process as detailed in the **Pre-Approval** procedure.
- Upon request by a PI or AUH.

Additional Use of BSL-1 Checklist

In addition to the IBC using the BSL-1 inspection checklist, when a PI submits an Exemption Form to the IBC for work with biological agents that do not pose a threat to human health or the environment they must also perform a self-inspection of their lab space, complete the BSL-1 checklist and submit it along with the Exemption Form. Following the submission to the IBC of the Exempt Form and BSL-1 checklist from the self-inspection, at a minimum the IBC Chair and Biosafety Officer will review and either approve and submit to the file, request additional information prior to approving, or determine a full protocol must be submitted.

Revision History		
Version No.	Brief Description of Changes	Created on Date
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI)	9/22/2023